JAN 15 2013

6 510(K) SUMMARY

A. Sponsor

Digirad® Corporation
13950 Stowe Drive
Poway, California 92064
Contact Person: Matthew Olow
Director, Quality and Regulatory Affairs
Tel: (858) 726-1309
Fax: (858) 726-1467

B. Date Prepared: November 1, 2012

C. Device Name

Trade Name:	ergo™ Imaging System
Common Name:	Camera, Scintillation (Gamma)
Classification Name:	Scintillation (gamma) camera
Device Class:	21CFR 892.1100, Class I
Product Code:	IYX

D. Cleared/Predicate Devices

The ergo Imaging System is substantially equivalent to the following cleared devices:

- ergo Imaging System, K100838
  Cleared on April 23, 2010
  Product Code: IYX
  CFR Section: 892.1100
  Device Class: Class I
  Classification Panel: Radiology

- LumaGEM Molecular Breast Imaging System, K111791
  Cleared on September 23, 2011
  Product Code: IYX
  CFR Section: 892.1100
  Device Class: Class I
  Classification Panel: Radiology

E. Device Description

The ergo Imaging System incorporates Digirad's Solid State RIM detector design with 3mm pixels for general purpose planar imaging, cleared under K100838. Sterile drapes are specified for intraoperative use. The ergo Imaging System, in conjunction with the optional

Breast Imaging Accessory (BIA), enables the user to perform scintimammography and extremity imaging with stabilization.

F. Intended Use & Indications for Use

The ergo Imaging System is intended to image the distribution of radionuclides in the body by means of a photon radiation detector. In so doing, the system produces images depicting the anatomical distribution of radioisotopes within the human body for interpretation by authorized medical personnel. The ergo Imaging System is used by trained medical personnel to perform nuclear medicine studies.

It is indicated for lymphatic scintigraphy and parathyroid scintigraphy, It can be used intraoperatively when protected by sterile drapes. It is also indicated to aid in the evaluation of lesions in the breast and other small body parts. When used for breast imaging, it is indicated to serve as an adjunct to mammography or other primary breast imaging modalities.

G. Technology

The ergo Imaging System utilizes Digirad's solid state detector technology comprised of arrays of thallium-doped cesium iodide crystal scintillators coupled to silicon photo diodes. Standard and optional collimators are available for different types of imaging.

H. Testing

Verification and Validation tests were conducted to demonstrate the ergo Imaging System functions per specification. These tests include Electromagnetic Compatibility, Electrical Safety, and gamma camera performance testing including NEMA standard NU 1-2007 with phantoms.

I. Conclusion

The ergo Imaging System that is the subject of this submission, is the same device that was cleared under K100838. Testing results demonstrate that the ergo Imaging System continues to meet the specifications and is substantially equivalent to the predicate devices, based on comparisons of intended use and technology, and overall system performance.

New indications are well-supported in the scientific literature, are routine applications of general-purpose gamma cameras, and have been demonstrated to be within the clinical capability of the ergo Imaging System. Therefore the new indications raise no new questions of safety or efficacy.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

Mr. Matthew Olow
Director, Quality and Regulatory Affairs
DIGIRAD Corporation
13950 Stowe Drive
POWAY CA 92064-8803

January 15, 2013

Re: K123408
Trade/Device Name: ergo Imaging System
Regulation Number: 21 CFR 892.1100
Regulation Name: Scintillation (gamma) camera
Regulatory Class: I
Product Code: IYX
Dated: November 1, 2012
Received: November 5, 2012

Dear Mr. Olow:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Michael D. O'Hara

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K123408

Device Name: ergo Imaging System

Indications for Use:

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Prescription Use ___X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)

(Division Sign Off)
Division of Radiological Health
Office of *In Vitro* Diagnostic and Radiological Health

510(k) K123408